

REMARKS

Claims 13 and 81 have been amended.

Claims 66-73 have been allowed.

35 U.S.C. §102

MPEP 2131 quotes Verdegaal Brothers v. Union Oil of California, 814 F.2d 628, 631 (Fed. Cir. 1987) for the legal standard of anticipation: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (emphasis added).

Claims 13-28

Amended claim 13 claims "[a]n integrated anastomosis tool for connecting a graft vessel having a lumen therein to a target vessel, comprising: a first mechanism configured to create an opening in the target vessel; a second mechanism configured to complete an anastomosis with the target vessel; a seal housing within which both said first mechanism and said second mechanism travel; and a single control configured to operate both said first mechanism and said second mechanism."

The seal housing 34 is a hollow structure to which an introducer tip 28 is connected. (e.g., page 13, line 23 through page 14, line 11; Figures 1A, 4). "The seal housing 34 includes an opening 36 at or near its distal end through which the introducer tip 28 and the auger assembly 10 extend" in an initial configuration. (page 14, lines 5-6) In that initial configuration, "[t]he cutter 4 extends proximally through the opening 36 in the seal housing 34." (page 14, lines 6-7). In use, the cutter 4 and auger 6 are actuated to create an opening in the wall of a target vessel. (e.g., page 28, line 6 through page 29, line 15; Figures 1A, 4, 37). "The cutter 4 and auger 6 are then retracted through the introducer tip 28. As they are

retracted, they retract the tissue plug, leaving an opening in the vessel wall. The introducer tip 28 follows the cutter 4 and the auger 6 into the vessel wall, and remains in the opening thus formed, in order to provide hemostasis with regard to that opening." (page 29, lines 15-20). The tissue plug is moved to "a location within the seal housing 34." (page 36, lines 17-18). The expander 260 and the crown 200 then "translate toward that opening through the introducer tube 62 into the seal housing 34." (page 56, lines 24-25; Figures 19-25, 31). The anastomosis device 140 is connected to the distal end of the crown 200. (e.g., page 43, lines 15-16; Figures 19-21, 36). "The motion of the expander 260 and crown 200 outside and in proximity to the opening in the target vessel wall takes place within the seal housing 34 in order to maintain hemostasis." (page 66, lines 3-5) "The crown 200, the anastomosis device 140 connected to the distal end of the crown 200, and the expander 260 [are then] translated distally into the introducer tip 52." (e.g., page 55, lines 20-22). The anastomosis device 140 is then deployed to complete an anastomosis between the graft vessel and the target vessel. (e.g., page 57, lines 12 through page 65, line 20). Thus, the specification discloses a first mechanism configured to create an opening in the target vessel, a second mechanism configured to complete an anastomosis with the target vessel, and a seal housing within which both the first mechanism and the second mechanism travel.

In contrast, U.S. Pat. No. 6,419,618 to Vargas ("Vargas") does not disclose a seal housing, much less the claimed "seal housing through which both said first mechanism and said second mechanism travel." Thus, Vargas neither expressly nor inherently describes each and every element claimed in amended claim 13, and Applicants believe amended claim 13 is in condition for allowance. Claims 14-28 depend from claim 13, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

Claims 58-65

This rejection is respectfully traversed.

Claim 58 claims "[a]n integrated anastomosis tool for connecting a graft vessel having a lumen therein to a target vessel, comprising: a first mechanism configured to create an opening in the target vessel; a second mechanism configured to complete an anastomosis with the target vessel; and a single control configured to operate both said first mechanism and said second mechanism; wherein at least a part of said first mechanism is moved along a first axis to create the opening in the vessel wall, and wherein said at least a part of said first mechanism is configured to move away from said first axis before said second mechanism deploys said anastomosis device."

In contrast, Vargas does not disclose a tool wherein at least a part of a first mechanism is moved along a first axis to create the opening in the vessel wall, and wherein at least part of the first mechanism is configured to move away from the first axis before a second mechanism deploys an anastomosis device. Rather, an anastomosis device is translated along the longitudinal axis of a trocar that is utilized to create the opening in the vessel wall. (*e.g.*, Figures 5-12).

Further, the claim limitation "wherein at least a part of said first mechanism is moved along a first axis to create the opening in the vessel wall, and wherein said at least a part of said first mechanism is configured to move away from said first axis before said second mechanism deploys said anastomosis device" contains the same language as claim 23. Claim 23 was objected to, rather than rejected, indicating that the subject matter of claim 23 is allowable. That subject matter is present in claim 58.

Thus, Vargas neither expressly nor inherently describes each and every element claimed in claim 58, and Applicants believe claim 58 is in condition for allowance. Claims

59-65 depend from claim 58, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

Claims 74-80

This rejection is respectfully traversed.

Claim 74 claims "[a]n integrated anastomosis tool for connecting a graft vessel having a lumen therein to a target vessel, comprising: a first mechanism configured to create an opening in the target vessel; a second mechanism configured to complete an anastomosis with the target vessel; a single control configured to operate both said first mechanism and said second mechanism; and a hollow introducer tip configured for placement at least partially into the opening in the target vessel, wherein at least a portion of said first mechanism and at least a portion of said second mechanism pass through said introducer tip."

The discussion above with regard to claim 13 applies equally here. Vargas does not disclose a hollow introducer tip configured for placement at least partially into the opening in the target vessel, wherein at least a portion of a first mechanism and at least a portion of a second mechanism pass through the introducer tip.

Thus, Vargas neither expressly nor inherently describes each and every element claimed in claim 74, and Applicants believe claim 74 is in condition for allowance. Claims 75-80 depend from claim 74, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

Claims 81-87

Amended claim 81 claims "[a]n integrated anastomosis tool for connecting a graft vessel having a lumen therein to a target vessel, comprising: a first mechanism configured to create an opening in the target vessel; a second mechanism configured to complete an

anastomosis with the target vessel; and a single control configured to operate both said first mechanism and said second mechanism, said single control rotatable about an axis substantially coaxial with the longitudinal centerline of said second mechanism; wherein at least one of said first mechanism and said second mechanism is at least partially lubricated with a biocompatible lubricious substance.”

In contrast, Vargas does not disclose a single control rotatable about an axis substantially coaxial with the longitudinal centerline of a mechanism configured to complete an anastomosis. (e.g., Figures 3, 9-12). Thus, Vargas neither expressly nor inherently describes each and every element claimed in amended claim 81, and Applicants believe amended claim 81 is in condition for allowance. Claims 82-87 depend from claim 81, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

35 U.S.C. §103

MPEP 706.02(j) states:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 1438 (Fed. Cir. 1991) (emphasis added).

Claims 19, 27, 28

Claims 19, 27 and 28 depend from independent claim 13, which is believed to be in condition for allowance, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

Claim 65

Claim 65 depends from independent claim 58, which is believed to be in condition for allowance, and is thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

Claim 80

Claim 80 depends from independent claim 74, which is believed to be in condition for allowance, and is thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

Claims 81-87

Amended claim 81 claims "[a]n integrated anastomosis tool for connecting a graft vessel having a lumen therein to a target vessel, comprising: a first mechanism configured to create an opening in the target vessel; a second mechanism configured to complete an anastomosis with the target vessel; and a single control configured to operate both said first mechanism and said second mechanism, said single control rotatable about an axis substantially coaxial with the longitudinal centerline of said second mechanism; wherein at least one of said first mechanism and said second mechanism is at least partially lubricated with a biocompatible lubricious substance."

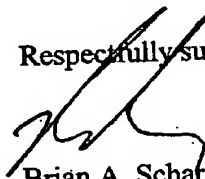
As set forth above, Vargas neither teaches nor suggests all of the limitations of claim 81. Further, U.S. Patent No. 6,004,909 to Lindman neither teaches nor suggests all of the limitations of claim 81. For example, Lindman describes a lubricant, but fails to disclose any structure whatsoever, much less a single control rotatable about an axis substantially coaxial with the longitudinal centerline of a mechanism configured to complete an anastomosis.

Neither Vargas nor Lindman, alone or in combination, teach or suggest all of the limitations of claim 81, and Applicants believe claim 81 is in condition for allowance. Claims 82-87 depend from claim 81, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

REQUEST FOR ALLOWANCE

Allowance of the pending claims is respectfully solicited. Please contact the undersigned if there are any questions.

Respectfully submitted,



Brian A. Schar
Attorney for Applicants
Reg. No. 45,076
Tel. No. (650) 331-7162

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